

Notice of Allowability	Application No.	Applicant(s)	
	09/084,837	LUTTICKEN ET AL.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS**. This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. This communication is responsive to April 4, 2002.

2. The allowed claim(s) is/are 32-39.

3. The drawings filed on 8/4/98 are accepted by the Examiner.

4. Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of the:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

1) hereto or 2) to Paper No./Mail Date _____.

(b) including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- 1. Notice of References Cited (PTO-892)
- 2. Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3. Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
- 4. Examiner's Comment Regarding Requirement for Deposit
of Biological Material
- 5. Notice of Informal Patent Application (PTO-152)
- 6. Interview Summary (PTO-413),
Paper No./Mail Date _____
- 7. Examiner's Amendment/Comment
- 8. Examiner's Statement of Reasons for Allowance
- 9. Other _____.

EXAMINER'S REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

Applicant's arguments and the declaration provided by Egbert Mundt submitted April 4, 2002 are found convincing. There is no teaching or suggestion in the prior art indicating that two nucleotide substitutions in the start codon of IBDV VP5 affects reversion. It is also evident from the data provided in the declaration that non-reversion of the IBDV VP5-2 recombinant is an unexpected result.

In addition to the prior art of record, the following references are considered pertinent to the instant invention:

Murphy et al. (US 5,993,824) claim an RSV genome recombinant comprising attenuating mutations to stabilize the virus against genetic reversion, see claim 1 and column 4, lines 5-15 and column 5, lines 36-53. A first mutation is a substitution at Met₁₁₆₉ within the RSV polymerase gene. This mutation is not required, as it is listed as an alternative to other mutations within the polymerase gene, and is not a start methionine. A second mutation is selected from multiple nucleotide substitutions in the gene-start sequence of gene M2. This sequence starts at nucleotide 7605 and is described as a non-coding sequence, i.e. not a start codon, see column 4, lines 5-11 and Figure 3. Therefore, the teachings of Murphy et al. do not teach or suggest substituting at least two nucleotides of a start methionine that prevents reversion to an undesirable phenotype.

In addition, the phenotypic results observed in the prior art for altered start codons are virus-specific. For example, Murphy et al. (Journal of Leukocyte Biology. 1994; 56 (3): 294-303, abstract only) teach that mutation of an HIV-1 Nef start codon reduces trans-activation.

However, none of the nucleotide start-methionine mutations to duck hepatitis B P28 had any affect on expression, see Fernholz et al. (Virology. 1993; 197 (1): 64-73, abstract only). In addition, Parkin et al. (US 5,690,937) caution that one or two nucleotide changes within a virus may be insufficient to prevent reversion, see column 3, line 43 to column 4, line 3. Therefore, the skilled artisan would not expect that two nucleotide substitutions at a start codon would result in a non-reverting phenotype.

Conclusion

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 6:00 AM - 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shanon Foley
Primary Examiner
Art Unit 1648